IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Art Unit: 1761

BOAKANG YANG Confirmation No.: 5923

APPLICATION NO: 10/091,149 Examiner: Becker, Drew E.

FILED: MARCH 4, 2002

FOR: JUICE BASED BEVERAGE COMPOSITIONS

RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Mail Stop: Appeal Brief – Patents Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

As set forth in the Notice of Appeal filed October 26, 2007, Appellant hereby appeals the Examiner's final rejection of claims 1-8, 10-22 and 24 of the above-identified application. Appellant respectfully requests that the Board of Patent Appeals and Interferences reverse the final rejection of these claims.

TABLE OF CONTENTS

		Page No.
I.	Real Party in Interest	3
II.	Related Appeals and Interferences	3
III.	Status of the Claims	3
IV.	Status of Amendments	3
V.	Summary of Claimed Subject Matter	3
VI.	Grounds of Rejection to be Reviewed on Appeal	4
VII.	Arguments	4
VIII.	Conclusion	8
IX.	Claims Appendix	9
X.	Evidence Appendix	13
ΧI	Related Proceedings Appendix	14

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Novartis AG.

II. RELATED APPEALS AND INTERFERENCES

At present, there are no other related appeals or interferences known to the Appellant and the Appellant's representative, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF THE CLAIMS

For the purposes of this Appeal, claims 1-8, 10-22, and 24, which are pending, stand finally rejected and are the subject of this appeal. Claims 9, 23 and 25-31 are cancelled without prejudice. Appealed claims 1-8, 10-22, and 24 are set forth in the Claims Appendix herewith.

IV. STATUS OF AMENDMENTS

On October 27, 2006, Appellant filed a "Response After Final Office Action" in reply to the Final Office Action" mailed May 30, 2006. The October 27th 2006 response included an amendment cancelling claims 9, 23, and 25-31. The Examiner issued an Advisory Action mailed November 9, 2006 withdrawing the rejections under 35 U.S.C. 112, second paragraph. The Advisory Action did not indicate whether Appellant's cancellation of claims 9, 23, and 25-31 was entered for the purpose of this Appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

This Appeal is taken from claims 1-8, 10-22, and 24, of which claim 1 is the only independent claim.

Claim 1 relates to an oral nutritional drink which is a clear fruit-juice based beverage composition comprising: (a) a source of protein in an amount from about 0.5 to about 10 wt % of the composition (see page 3, lines 4-5 and 17-18; page 5, lines 14-15; page 6, lines 22-23 of the specification), wherein the protein source is a combination of whey protein isolate and whey protein hydrolysate (see page 3, lines 19-20; page 5, lines 16-17; and page 6, lines 24-25 of the specification); (b) a source of carbohydrate in an amount from about 1 to about 30 wt % of the composition (see page 3, lines 5-6 and 20-21; page 5, line 18; and page 7,

lines 1-11 of the specification); (c) a source of edible acids in an amount from about 0.01 to about 3 wt % of the composition (see page 3, lines 6-7 and 24-25; page 5, lines 22-23; and page 7, lines 23-24 of the specification); and (d) a source of fruit juices in an amount from about 5 to about 40 wt % of the composition (see page 3, lines 7-8 and 29-30; and page 5, lines 26-27 of the specification).

Support for the claimed features can also be found in the Examples illustrated in the specification.

There are no means plus function claims under 35 U.S.C. §112, sixth paragraph in this appeal.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant respectfully requests the Board to reverse the following grounds of rejection:

- (A) The rejection of claims 1-8, 10-20, and 22-24 under 35 USC §103(a) as being obvious over U.S. 6,106,874 to Liebrecht et al. (hereinafter "Liebrecht"), in view of GB2335134A to (hereinafter "Burke"); and
- (B) The rejection of claim 21 under 35 USC §103(a) as being obvious over Liebrecht, in view of Burke, and further in view of JP 4-311378A to Harada et al. (hereinafter "Harada").

VII. ARGUMENTS

A. The rejection of claims 1-8, 10-20 and 22-24 under 35 USC §103(a) as being obvious over Liebrecht, in view of Burke

Claims 1-8, 10-20 and 22-24 stand rejected under 35 USC §103(a), as being obvious over Liebrecht, in view of Burke.

Liebrecht relates to a beverage as a source of calcium (abstract) does not disclose the use of whey protein hydrolysates. Burke relates to a carbonated sports drink of high caloric value for people engaged in physical activities. Burke states that protein hydrolysates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels of specific carbohydrates to prevent this precipitation. Burke and Liebrecht are nutritional beverages based on fruit juice, carbohydrate and protein. Can Liebrecht, in view of Burke render claims 1-8, 1-20 and 22-24 unpatentable under 35 U.S.C. §103(a) when protein

hydrolysates have a problem that they tend to precipitate and Burke only provides the solution in a specific range of carbohydrate amounts and of carbohydrates of a specific nature?

As admitted by the Examiner, Liebrecht does not disclose the use of whey protein hydrolysates.

Appellant respectfully submits that this rejection is improper because a prima facie case of obviousness has not been established. The three elements of a prima facie case of obviousness are: 1) some suggestion or motivation to modify the reference or combine the teachings; 2) a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Burke relates to a carbonated sports drink of high caloric value people engaged in physical activities, and Liebrecht is specifically for providing calcium supplementation. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Neither reference suggests the desirability of the combination since their intended uses are dramatically varied. The Examiner states that since both Burke and Liebrecht are nutritional beverages based on fruit juice, carbohydrate and protein, it would be obvious to combine them. Appellant respectfully disagrees, especially in light of no suggestion in either reference of the desirability of the combination. Appellant respectfully submits that there is no suggestion or motivation in Burke or Liebrecht to modify the reference or combine the teachings. "Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making" the necessary modification. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051 5 U.S.P.Q.2d 1434, 1438 (Fed Cir. 1988), cert. denied, 488 U.S. 825 (1988)

Turning now to the second element of obviousness, there is no reasonable expectation of success. Contrary to a reasonable expectation of success, Burke states that protein hydrolysates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels of specific carbohydrates to prevent this precipitation; it should be noted that Burke (page 3, lines 22-28) states that the problem was solved by adjusting the amount and nature of the carbohydrate used but does not elaborate on the nature of that carbohydrate. Further in the present application at page 1, line 11, it describes that "The development of fruit juice based beverages containing proteins, carbohydrates, vitamins, and minerals is very difficult. The interaction of the ingredients, particularly the protein with the minerals and other ingredients, often cause the protein to precipitate and frequently cause the entire composition to

become very viscous or to gel. Similarly, these interactions may change the physical or chemical properties of the composition in a way that adversely affects the taste, color, odor, mouth-feel and other physical properties of the composition. These adverse changes may occur at any time but are particularly likely when the composition is heated during processing or when the composition sits on the shelf for extended periods." The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986); MPEP 2143.02. In the present case, however, there is no reasonable expectation of success without undue experimentation. Neither reference teaches or suggests that the addition of protein hydrolysates will illicit a clear beverage and not cause the problems of precipitation when added to a composition, as described and claimed in the present invention.

In the Advisory Action, the Examiner has asserted that this element is addressed in Burke at page 3, line 28. However, page 3, line 28 does not address the combination of the present invention as claimed. A reading of Burke would not teach one of ordinary skill in the art how to add protein hydrolysates to any mixture without causing the protein to precipitate and not render a clear composition, Burke only discloses a carbonated beverage that will not precipitate on storage with the components and ratios of components described in Burke. Therefore, combination of Burke and Liebrecht are believed to be not proper.

In the Advisory Action, the Examiner has asserted that this element (a clear beverage and not cause the problems of precipitation) is addressed in Liebrecht at column 1, line 7. However, column 1, line 7 does not address a clear liquid when protein hydrolysates have been added, which, as argued above would likely cause the protein to precipitate and not render a clear composition. Liebrecht at column 1, line 7 only describes a clear beverage with the components and ratios of components described in Leibrecht, which, as admitted by the Examiner does not include whey protein.

Even if Liebrecht and Burke were to be combined, the solution proposed by Appellant would not be achieved since they still would not teach how to combine the ratio of ingredients claimed in claim 1, nor obtain a clear, palatable beverage, without precipitate of the protein.

Because on the above reasons presented hereinabove, Appellant respectfully submits that the Examiner has failed to establish *prima facie* obviousness of independent claim 1. Accordingly, Appellant respectfully requests the Board to reverse the final rejection of claim 1.

Because claims 2-8, 10-20, 22 and 24 (claim 23 was previously cancelled) depend from claim 1, Appellant respectfully submits that these dependent claims are also patentable over Liebrecht, in view of Burke, at least for the reasons set forth hereinabove. Accordingly, Appellant also respectfully requests the Board to reverse the final rejection of these dependent claims.

(B) The rejection of claim 21 under 35 USC §103(a) as being obvious over Liebrecht, in view of Burke, and further in view Harada

Claim 21 stands rejected under 35 USC §103(a), as being obvious over Liebrecht, in view of Burke, and further in view of Harada. Liebrecht and Burke are discussed above and the grounds are herein incorporated. Harada relates to a specific fiber supplement. Can Liebrecht, in view of Burke, and further in view of Harada render claim 21 unpatentable under 35 USC §103(a) when protein hydrolysates have a problem that they tend to precipitate and Burke only provides the solution in a specific range of carbohydrate amounts and of carbohydrates of a specific nature?

The arguments for claims 1-8, 10-20, 22 and 24 are relevant for claim 21 and are herein incorporated. There is no motivation to combine Liebrecht, Burke and Harada since Liebrecht is specifically for providing calcium supplementation, Burke is specifically a high calorie sports drink and Harada deals with fiber supplementation. Each designed to address very different issues. There must be a teaching in the prior art for the proposed combination or modification to be proper. *In re Newell*, 13 U.S.P.Q.2d 1248 (Fed Cir. 1989). There is no such teaching or suggestion in Liebrecht, Burke or Harada, to combine these references.

Appellant submits that even if a skilled person were to combine the teaching of Liebrecht, Burke and Harada, the solution proposed by Appellant would not be achieved. As described above regarding paragraph 5, that "The development of fruit juice based beverages containing proteins, carbohydrates, vitamins, and minerals is very difficult. The interaction of the ingredients, particularly the protein with the minerals and other ingredients, often cause the protein to precipitate and frequently cause the entire composition to become very viscous or to gel." Also as stated above, Burke states that protein hydrolysates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels and nature of carbohydrates to prevent this precipitation. Since fiber supplements are generally carbohydrates, the solution of Burke would not teach one of ordinary skill in the art how to add a fiber, not disclosed in Burke, to a solution and not have the protein hydrolysates precipitate. Therefore, the combined

references would not teach or suggest how to make a clear, palatable beverage, without precipitate of the protein.

Based on the above-mentioned remarks, Appellant respectfully submits that the Examiner has failed to establish *prima facie* obviousness of claim 21. Accordingly, Appellant respectfully requests the Board to reverse the final rejection of claim 21.

VIII. CONCLUSION

FOR THESE REASONS, Appellant respectfully petitions this Honorable Board to reverse the rejections of claims 1-8, 10-22 and 24 based on the reasons set forth above. Should the Board have any questions about the above remarks, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

January 22, 2008

Date:

Reg. No. 48,627 for
Raymond Van Dyke (Reg. No. 34,746)

WINSTON & STRAWN LLP

Customer No. 28765

(202) 282-5971

IX. CLAIMS APPENDIX

- 1. A clear fruit-juice based beverage composition comprising:
- (a) a source of protein in an amount from about 0.5 to about 10 wt % of the composition, wherein the protein source is a combination of whey protein isolate and whey protein hydrolysate;
- (b) a source of carbohydrate in an amount from about 1 to about 30 wt % of the composition;
- (c) a source of edible acids in an amount from about 0.01 to about 3 wt % of the composition; and
- (d) a source of fruit juices in an amount from about 5 to about 40 wt % of the composition.
- 2. The composition of claim 1 wherein the composition is clear, has a pH of 4.0 or less, and has a viscosity of less than about 40 centipoises.
- 3. The composition of claim 2 the composition has a viscosity of less than 20 centipoises.
- 4. The composition of claim 1 wherein the source of fruit juices is in an amount from about 10 to about 40 wt %.
- 5. The composition of claim 1 wherein the source of carbohydrate comprises from about 5 to about 25 wt % of the composition.
- 6. The composition of claim 1 wherein the source of carbohydrate comprises from about 8 to about 20 wt % of the composition.

- 7. The composition of claim 1 wherein the source of protein comprises from about 2 to about 8 wt % of the composition.
- 8. The composition of claim 1 wherein the source of edible acids comprises from about 2 to about 7 wt % of the composition.
- 10. The composition of claim 1 wherein whey protein hydrolysate comprises up to 20 wt % of the combination.
- 11. The composition of claim 1 wherein the carbohydrate source comprises at least one carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, HFCS 55 and maltodextrin.
- 12. The composition of claim 1 wherein the source of carbohydrate is a combination of maltodextrin and at least one other carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, and HFCS 55, and wherein maltodextrin comprises up to about 25 wt % of the combination.
- 13. The composition of claim 1 wherein the source of edible acids comprises at least one edible acid selected from the group consisting of citric acid, phosphoric acid, and malic acid.
- 14. The composition of claim 1 wherein the source of edible acids comprises a combination of malic acid and at least one other edible acid selected from the group consisting of citric acid and phosphoric acid, and wherein malic acid comprises up to about 30 wt % of the combination.
- 15. The composition of claim 1 further comprising from about one-tenth to about three times the recommended daily allowance of one or more minerals.

- 16. The composition of claim 1 further comprising at least one mineral selected from the group consisting of calcium, potassium, magnesium, iron, sodium, iodine, molybdenum, chromium, selenium, zinc, and copper.
- 17. The composition of claim 1 further comprising at least one water-soluble vitamin.
- 18. The composition of claim 1 further comprising at least one vitamin selected from the group consisting of vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, panthotenic acid, biotin, folic acid, and niacin.
- 19. The composition of claim 1 further comprising up to about 5 wt % of the composition of at least one fiber selected from the group consisting of pectin, cellulose gum, xanthan gum, gum arabic, polydextrose, inulin, and arabinogalactan.
- 20. The composition of claim 1 further comprising up to about 5 wt % of the composition of at least one fiber selected from the group consisting of polydextrose, inulin, and arabinogalactan.
- The composition of claim 1 further comprising from about 0.5 wt % to about 4% of the composition of at least one fiber selected from the group consisting of polydextrose, inulin, and arabinogalactan
- 22. The composition of claim 1 further comprising up to about 0.1 wt % of the composition of at least one fiber selected from the group consisting of pectin, cellulose gum, xanthan gum, and gum arabic.

24. The composition of claim 1 wherein the carbohydrate source is a combination of sucrose and fructose.			

X. EVIDENCE APPENDIX

There is no related evidence submitted with this Appeal.

XI. RELATED PROCEEDINGS APPENDIX

There are no other related proceedings related to this appeal.